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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/511,824 02/24/00 YAMAO

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EXAMINER

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ART UNIT	PAPER NUMBER
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1641

DATE MAILED:

08/02/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/511,824</b>	Applicant(s) <b>Yama et al.</b>
	Examiner <b>Gallene R. Gabel</b>	Group Art Unit <b>1641</b>

Responsive to communication(s) filed on Feb 24, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 8-12 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 8-12 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) 08/914,039.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

**-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --**

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## **DETAILED ACTION**

### ***Amendment Entry***

1. Applicants' preliminary amendment filed 2/24/00 is acknowledged and has been entered. Claims 1-7 have been canceled. Claims 8-12 have been added. Accordingly, claims 8-12 are pending and under examination.

### ***Priority***

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/914,039, filed on 7/28/97.

### ***Specification***

3. This application filed under former 37 CFR 1.60 has the necessary reference to the prior application in the first sentence of the specification. However, the current status of the nonprovisional parent applications referenced should also be included.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8, line 4 is vague and indefinite in reciting "onto which antibodies specifically reacting with the antigens in the whole blood are immobilized" because it appears to intend for the antibodies to be "reacting" with the antigens (a method step) while being immobilized onto the insoluble carriers. The following language is suggested but not required: --onto which antibodies specific for the antigens in the whole blood are immobilized--.

The term "substantially" in claim 8 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also claim 9.

Claim 9, line 4 is confusing in reciting "adding a hemolysis reagent ... without any pre-treatment of the whole blood because it is unclear what element or method step applicants intend to encompass by "any pre-treatment of the whole blood". For example, elements or method steps that include pre-treatment are EDTA for anticoagulation, centrifugation for separation, vortexing for lysis, DI water for lysis. Further, it is unclear what the structural or functional cooperative relationship is between the "hemolysis reagent" and the "any pre-treatment step".

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Claim 9, line 9 has improper antecedent basis problem in reciting "a predetermine antigen".

It is unclear what the structural cooperative relationship is between the "reaction mixture" in claim 9, line 9 and the "reaction products" in line 11.

In claim 9, line 11, insert "s" after include to correct grammar.

Claim 9, line 14 has improper antecedent basis problem in reciting "a wavelength range".

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 9-12 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-10 of prior U.S. Patent No. 6,030,845. This is a double patenting rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradwell et al. (US 4,889,815).

Bradwell et al. disclose an immunoassay system comprising a means for lysing whole blood with a hemolysis reagent (cuvette made of transparent suitable material charged with lysing reagent such as saponin/KCN). The system further comprises a means for reacting antigens in the whole blood sample to form a reaction mixture comprising insoluble carriers with antibodies immobilized thereto (latex bound antibodies) (see column 3, lines 16-33). The system further includes a nephelometer for use in analysing the reactions in whole blood without the need to remove blood cells or hemoglobin (see column 1, lines 51-54). A second detector is included to compensate for the amount of light absorbed possibly by the hemoglobin in the sample to minimize and correct for any degree of absorption by the hemoglobin in the sample (see column 1, lines 21-25, 51-54; column 3, lines 16-54 ; column 4, lines 59-61). In the system, wavelength is read where the strength of radiation scattered by antigen/antibody complex is high and the absorption by hemoglobin and other proteins is low.

Bradwell et al. differ in failing to teach a means for determining hematocrit percent and a means for calculating a plasma concentration such as provided in claim 8 to mathematically correct for hemoglobin content. However, hematocrit is a measure of the amount of red blood

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cells present in a whole blood and means of measurement thereof is well-known ranging from simple capillary tube centrifugation to highly automated hematological analyzers. It would further have been obvious and well within ordinary skill in the art to mathematically correct for hemoglobin concentration based upon measured hematocrit values, which inherently represents the amount of red blood cells present in the whole blood and thus, indirectly approximate the amount of hemoglobin present in the sample since calculations involving correction factors to arrive at a true mathematical value, i.e. concentration, is conventional and the hypothetical person of ordinary skill presumably must have some level of skill in so doing.

7. No claims are allowed.

***Information Disclosure Statement***

8. The information disclosure statement filed 2/24/00 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. References O and P were not considered because neither a copy, an English translation, nor a statement of relevancy was provided therefor.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The

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examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays at 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*gngabel 7/30/00*

Gailene R. Gabel  
Patent Examiner  
Art Unit 1641

*Long Le*

LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600